PARCHE DE LEON- lidocaine, menthol patch Pharmadel LLC

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

Parche Leon Gel Patch (SHANGHAI G)

Drug Facts

Active Ingredients & Purpose

Active ingredients (in each patch)	Purpose
Lidocaine 4%	External analgesic
Menthol 1%	External analgesic

Uses

For the temporary relief of pain.

Warnings

FOR EXTERNAL USE ONLY. Avoid contact with the eyes.

Do not use

- in large quantities, particularly over raw surfaces or blistered areas
- on sensitive skin
- if allergic to any ingredients in this product

Stop use and ask a doctor if

- condition worsens
- symptoms persist for more than 7 days or clear up and occur again within a few days
- redness is present

If pregnant of breast-feeding

ask a health professional before use.

KEEP OUT OF REACH OF CHILDREN.

If swallowed, get medical help or contact a Poison Control Center right away.

Directions

- adults & children 12 years of age and older: apply to affected area not more than 3 to 4 times daily
- children under 12 years of age: consult a doctor
- clean dry affected area
- remove patch from film
- apply sticky side of patch to affected area
- use one patch at a time
- leave patch on affected area for up to 8-hours at a time

Other Information

- store at room temperature 59-86 F (15-30 C)
- do not store in direct sunlight or expose to excessive heat

TAMPER EVIDENT: Do not use if packet containing the patch is torn or broken.

Inactive Ingredients

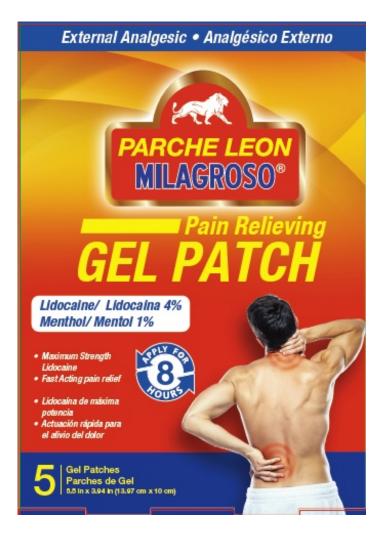
dihydroxyaluminum aminoacetate anhydrous, edetate disodium, glycerin, hydroxyacetophenone, kaolin, mineral oil, polyacrylic acid,

polysorbate 80, propylene glycol, povidone k90, sodium polyacrylate, tartaric acid, titanium dioxide, water

Principal Display Panel

5 Patches (5.5 in x 3.94 in (13.97 cm x 10 cm) each)

- Maximum Strength
- Fast Acting pain relief
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PARCHE DE LEON lidocaine, menthol patch					
Product Information					
Product Type	HUMAN OTC DRUG	Item Code (Source)		NDC:55758-040	
Route of Administration	TOPICAL				
Active Ingredient/Active Moiety					
Ingr	edient Name		Basis of S	trength	Strength
LIDOCAINE (UNII: 98PI200987) (LIE	OCAINE - UNII:98PI200987)		LIDOCAINE		4 g
MENTHOL, UNSPECIFIED FORM FORM - UNII:L7T10EIP3A)	(UNII: L7T10EIP3A) (MENTH	OL, UNSPECIFIED	MENTHOL, UN FORM	ISPECIFIED	1 g
Inactive Ingredients					
	Ingredient Name	•		S	trength
EDETATE DISODIUM (UNII: 7FLD9	1C86K)				
PROPYLENE GLYCOL (UNII: 6DC9	Q167V3)				
WATER (UNII: 059QF0KO0R)					
DIHYDROXYALUMINUM AMINOA	CETATE ANHYDROUS (UNI	ll: 1K713C615K)			

POVIDONE K90 (UNII: RDH86HJV5Z)	
KAOLIN (UNII: 24H4NWX5CO)	
POLYSORBATE 80 (UNII: 60ZP39ZG8H)	
POLYACRYLIC ACID (800000 MW) (UNII: D0I6NSZ87U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
GLYCERIN (UNII: PDC6A3C0OX)	
SODIUM POLYACRYLATE (8000 MW) (UNII: 285CYO341L)	
TARTARIC ACID (UNII: W4888I119H)	
HYDROXYACETOPHENONE (UNII: G1L3HT4CMH)	
MINERAL OIL (UNII: T5L8T28FGP)	

Packaging

#	ltem Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55758-040- 05	5 in 1 CARTON	03/18/2022	
1	NDC:55758-040- 01	1 in 1 POUCH; Type 0: Not a Combination Product		
2	NDC:55758-040- 01	1 in 1 POUCH; Type 0: Not a Combination Product	03/18/2022	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part348	03/18/2022		

Labeler - Pharmadel LLC (030129680)

Revised: 12/2022

Pharmadel LLC